UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

JOHNNY POLK, individually and on behalf of all others similarly situated,	)	
	)	
***Plaintiff*,**	)	
	)	
v.	)	**Case No.: 4:09-CV-00588 SNLJ**
	)	
KV PHARMACEUTICAL COMPANY, and THER-RX CORPORATION,	)	
	)	
***Defendants*.**	)	

MEMORANDUM

Plaintiff has filed this multi-count putative class action against Defendants KV Pharmaceutical Company and Ther-Rx Corporation, alleging violations of the Missouri Merchandising Practices Act and breach of the implied warranty of merchantability in connection with Plaintiff's purchase of Metoprolol Succinate ER Tablets manufactured and marketed by Defendants [66]. This matter is before the Court on Defendants' motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, filed July 28, 2011 [69]. Responsive pleadings have now been filed and this matter is ripe for disposition.

I. BACKGROUND

Defendant KV Pharmaceutical Corporation (hereinafter "KV Pharmaceutical") is a corporation incorporated under the laws of Delaware, with its principal place of business in Bridgeton, Missouri. KV Pharmaceutical is engaged in the business of manufacturing, processing, labeling, holding, and distributing prescription and non-prescription drugs. Defendant Ther-Rx Corporation (herinafter "Ther-Rx") is a marketing subsidiary of KV Pharmaceutical organized under the laws of Missouri, with its principal place of business in

Bridgeton, Missouri. Ther-Rx is engaged in the business of marketing and distributing pharmaceutical drugs, including those manufactured by KV Pharmaceutical.

Plaintiff Johnny Polk was prescribed and began taking Metoprolol Succinate ER Tablets (hereinafter "the Medication") approximately ten years ago. Throughout 2007, 2008, and 2009, Plaintiff's prescription for the Medication was filled at Walgreen's Pharmacy in DeSoto, Texas. During the relevant time period, the DeSoto, Texas Walgreen's purchased its inventory of the Medication from the Defendants.

In December, 2008 and February, 2009, the Food and Drug Administration conducted inspections of KV Pharmaceutical's production facilities and documented 35 deviations from current good manufacturing practices. Following the inspections, the FDA formally alleged that Defendants were not in compliance with current good manufacturing practices and therefore the Medication produced in the facilities was adulterated. Ultimately, the FDA and the Defendants settled the dispute by entering into a Consent Decree and Permanent Injunction [16-3]. In the Consent Decree, the FDA made no findings of fact regarding the alleged non-compliance. Rather, the Consent Decree merely contains the allegations levied by the FDA against the Defendants which the Defendants neither admitted nor denied. Among the FDA's allegations, the FDA alleged that by entering into the stream of commerce the subject Medication which did not comply with current good manufacturing practices, Defendants placed into the stream of commerce drugs that were "adulterated" within the meaning of 21 U.S.C. §351(a)(2)(B). 21 U.S.C. § 351(a)(2)(B) provides a drug is considered adulterated if:

> it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess[.]

21 U.S.C. § 351(a)(2)(B). As a condition of their settlement with the FDA, Defendants issued a retail level recall covering all then existing inventories of the Medication in January 2009. The recall did not extend to end-users or patients who had already purchased the Medication.

II. LEGAL STANDARD

The purpose of a Rule 12(b)(6) motion to dismiss for failure to state a claim is to test the legal sufficiency of a complaint so as to eliminate those actions "which are fatally flawed in their legal premises and designed to fail, thereby sparing litigants the burdens of unnecessary pretrial and trial activity." Young v. City of St. Charles, 244 F.3d 623, 627 (8th Cir. 2001) (quoting Neitzke v. Williams, 490 U.S. 319, 326-27 (1989)). A complaint must be dismissed for failure to state a claim it if does not plead "enough facts to state a claim to relief that is plausible on its face." Bell Atlantic v. Twombly, 550 U.S. 544, 560 (2007) (abrogating the traditional "no set of facts" standard set forth in Conley v. Gibson, 355 U.S. 41, 45-46 (1957)). A petitioner need not provide specific facts to support his allegations, Erickson v. Pardus, 551 U.S. 89, 93 (2007) (per curiam), but "must include sufficient factual information to provide the 'grounds' on which the claim rests, and to raise a right to relief above a speculative level." Schaaf v. Residential Funding Corp., 517 F.3d 544, 549 (8th Cir. 2008) (quoting Twombly, 550 U.S. at 555-56 & n.3), *cert. denied,* 129 S.Ct. 222 (2008).

In ruling on a motion to dismiss, a court must view the allegations of the complaint in the light most favorable to the petitioner. Schuer v. Rhodes, 416 U.S. 232 (1974); Kottschade v. City of Rochester, 319 F.3d 1038, 1040 (8th Cir. 2003). Although a complaint challenged by a Rule 12(b)(6) motion does not need detailed factual allegations, a petitioner must still provide the grounds for relief, and neither "labels and conclusions" not "a formulaic recitation of the elements of a cause of action" will suffice. Twombly, 550 U.S. at 555 (internal citations

omitted). "To survive a motion to dismiss, a claim must be facially plausible, meaning that the 'factual content . . . allows the court to draw the reasonable inference that the respondent is liable for the misconduct alleged.'" Cole v. Homier Dist. Co., 599 F.3d 856, 861 (8th Cir. 2010) (quoting Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009)). When determining the facial plausibility of a claim, the Court must "accept the allegations contained in the complaint as true and draw all reasonable inferences in favor of the nonmoving party." Id. (quoting Coons v. Mineta, 410 F.3d 1036, 1039 (8th Cir. 2005)).

Finally, when reviewing a Rule 12(b)(6) motion, if documents outside the pleadings are presented and not excluded, the motion must be treated as a motion for summary judgment. Rule 12(d) Fed. R. Civ. Pro. Documents that are necessarily embraced by the pleadings are not "matters outside the pleadings" for purposes of Rule 12(d). Enervations, Inc. v. Minnesota Mining & Mfg. Co., 380 F.3d 1066, 1069 (8th Cir. 2004); *see also* Zoltek Corp. v. Structural Polymer Grp., 2008 WL 4921611, *2 (E.D. Mo. 2008) *rev. on other gds.* Zoltek Corp., 592 F.3d at 893 (8th Cir. 2010). The documents, including but not limited to the FDA Consent Decree, attached to the complaint are necessarily embraced by the pleadings and can be considered under the instant 12(b)(6) motion without converting the instant dismissal motion to a motion for summary judgment. In making its ultimate decision, the Court has not considered any other exhibits that may have been filed by either party that are not necessarily embraced by the pleadings.

III. DISCUSSION

A. Effect of The FDA Consent Decree

Plaintiff's Missouri Merchandising Practices Act and breach of the implied warranty of merchantability claims rely heavily on the Consent Decree entered into between Defendants and

the FDA. Plaintiff alleges that the Defendants' assent to the Consent Decree merits the legal conclusion that the Medication was adulterated and defective when purchased by the Plaintiff. Plaintiff appears to be attempting to use the Consent Decree to collaterally estop the Defendants from denying that they violated the MMPA and breached the implied warranty of merchantability.

The Consent Decree's preamble provides:

> [The FDA] and Defendants while disclaiming any liability in connection therewith, having appeared and consented to entry of this Consent Decree of Permanent Injunction ("Decree") without contest and before any testimony has been taken, *solely for the purpose of settling this case*, and *without admitting or denying the allegations* in the Complaint, and the United States of America, having consented to this Decree . . . .

Consent Decree of Permanent Injunction, at 2 (emphasis added). The Consent Decree further provides "[t]he Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 . . . , *and alleges*: . . . . " Consent Decree of Permanent Injunction, at 2 ¶ 3 (emphasis added).

The Consent Decree entered into between Defendants and the FDA is unambiguous. The Consent Decree clearly provides that Defendants disclaim any liability arising out of the Consent Decree, and Defendants do not admit or deny the allegations of the FDA's complaint. Further, the Consent Decree contains no findings of fact or legal conclusions. The Consent Decree contains only allegations levied by the FDA regarding 35 probable deviations from current good manufacturing practices. The FDA's allegations are not conclusive proof of wrongdoing by Defendants and will not be afforded such treatment by the Court.

Plaintiff argues that Defendants' disclaimer of liability in the Consent Decree is "inconsequential." Plaintiff, citing Swift & Co. v. United States, 276 U.S. 311 (1928); Donaghy v. City of Omaha, 933 F.2d 1448 (8th Cir. 1991); and EEOC v. AT&T, 419 F.Supp. 1022 (E.D.

Pa. 1976); contends that both the Supreme Court and the Eighth Circuit Court of Appeals have long held that language disclaiming liability in a consent decree is a standard feature of consent decrees having no real significance, and therefore disclaimers do not prevent future litigation based upon the contents of a consent decree. However, the limited facts of the cases cited by the Plaintiff are significantly distinguishable from the present case. Most importantly, none of the Plaintiff's cited cases involved a non-party to a consent decree attempting to use the consent decree entered into by a defendant in a previous administrative action as the basis for a later independent lawsuit against the defendant. For example, in Swift & Co., the Supreme Court was examining the validity of a consent decree in the face of a motion to vacate the consent decree whereas in this case the validity of the Consent Decree is not at issue. Swift & Co., 276 U.S. at 324. In AT&T, the United States District Court for the Eastern District of Pennsylvania, in ruling on a series of motions attempting to modify or supplement an existing consent decree, noted that "the failure of a party to a consent decree to admit liability for alleged misconduct does not affect *the validity of the consent decree itself*." AT&T, 419 F.Supp. at 1038 n.16 (emphasis added).

In the present case there is no challenge to the validity of the Consent Decree. Defendants are not asking the Court to vacate the Consent Decree. Rather, Plaintiff is asking the Court to impute unto the Consent Decree the force of a judgment against Defendants on the merits when no such judgment was ever entered by any court. Given the limited scope of the instant case, the Court cannot, and will not, consider the Consent Decree to be an adverse judgment on the merits against the Defendants.

In Donaghy v. City of Omaha, the Eighth Circuit Court of Appeals examined a consent decree in the context of evaluating an affirmative action plan. 933 F.2d at 1460. In Donaghy, a

Caucasian police officer sued the City of Omaha claiming he was passed over for a promotion in favor of a less qualified minority candidate. In evaluating the actions of the City of Omaha, the Eighth Circuit examined the affirmative action plan utilized by the city in promoting minority police officers to determine if the plan served a remedial purpose. The affirmative action plan was created under the direction of a consent decree entered into between the City of Omaha and the United States, and the consent decree outlined certain standards the City of Omaha was required to meet. In evaluating a challenge to the consent decree which created the affirmative action plan and concluding that the plan served a remedial purpose, the Eighth Circuit noted that the City's disclaimer of liability in the consent decree carried "little weight" in determining whether or not the plan served a remedial purpose. Id. In Donaghy, the Eighth Circuit rejected an attempt by the defendant to use a disclaimer of liability in a consent decree as a shield to protect itself from liability for failing to promote the plaintiff under the subject affirmative action plan. The Eighth Circuit did not hold, however, that a third party plaintiff was entitled to use a consent decree containing a disclaimer of liability as the basis for an independent lawsuit against the same defendant.

The subject Consent Decree contains only allegations that were neither admitted nor denied by Defendants; as well as the express denial of liability by the Defendants. In light of the circumstances giving rise to the Consent Decree, and the language contained in it, the Court can only consider it as evidence that a settlement was reached between the Defendants and the FDA.

B. Violations of the Missouri Merchandising Practices Act

In order to state a claim under the Missouri Merchandising Practices Act (hereinafter the "MMPA"), a plaintiff must first show that he or she purchased the merchandise in question; second, that he or she purchased the merchandise for personal, family, or household use; third,

that he or she suffered an ascertainable loss; and fourth, the ascertainable loss was the result of an unfair practice. Mo. Rev. Stat. 407.025(1). It is undisputed that Plaintiff purchased the Medication. Also, it is undisputed that Plaintiff purchased the Medication for personal, family, or household use. The next question is whether or not Plaintiff suffered an ascertainable loss.

Missouri courts apply the "benefit of the bargain" rule when determining if a plaintiff has suffered an ascertainable loss under the MMPA. Sunset Pools of St. Louis, Inc. v. Schaefer, 869 S.W.2d 883, 886 (Mo. Ct. App. 1994). The "benefit of the bargain" rule awards a defrauded party the difference between the value of the product as represented and the actual value of the product as received. Id.

Plaintiff alleges that the Medication he and others in the putative class of plaintiffs received was "adulterated" Medication, and because the Medication was adulterated, it was therefore completely worthless. Plaintiff, citing Plubell v. Merck & Co., Inc., argues that because he alleged that the Medication was worth less than what he paid for it, he has alleged an ascertainable loss sufficient to state a claim under the MMPA. 289 S.W.3d 707 (Mo. Ct. App. 2009). In Plubell, Merck, the maker of the prescription anti-inflammatory and pain medication Vioxx, was sued under the MMPA amidst allegations that Merck denied and concealed survey results which indicated Vioxx posed significant undisclosed health risks to consumers. Id. at 711. On appeal, Merck argued that the plaintiffs had not sufficiently pleaded an ascertainable loss as required by the MMPA. Id. at 715. The Missouri Court of Appeals rejected Merck's argument, ruling that "because Plaintiffs alleged Vioxx was worth less than the product as represented, they stated an objectively ascertainable loss under the MMPA using the benefit of the bargain rule." Id. Plaintiff's claims in the present action are significantly different than the claims asserted in Plubell. In Plubell, the plaintiffs specifically alleged that the product they

purchased posed significant risks to their health and was therefore worth less than what they bargained for in purchasing the product. In the present case, Plaintiff alleges only that in a prior agency action the FDA alleged the product purchased was "adulterated" under the FDA's current good manufacturing practices, not that it was a health risk to consumers. Unlike Plubell, where the plaintiffs specifically alleged misrepresentations of the nature and quality of the product purchased, Plaintiff in the present case has asserted only the legal conclusion of product defect due to "adulteration." Plaintiff has not alleged the Medication was anything other than what it has always purported to be. Further, Plaintiff failed to allege he did not receive the benefit from the Medication for which he bargained; i.e. the medication did not perform as intended. *See* In re Bisphenol-A (BPA) Polycarbonate Products Liability Litigation, 687 F.Supp. 2d 897, 912-13 (W.D. Mo. 2009) (rejecting as basis of liability theory that purchaser would have paid less for product had purchaser known of defect when purchaser used product with latent defect, product performed as anticipated, and purchaser received full benefit of the bargain).

The present case is strikingly similar to Myers-Armstrong v. Actavis Totowa, LLC, 2009 WL 1082026 (N.D. Cal., April 22, 2009). In Myers-Armstrong, the plaintiff alleged that a drug produced in violation of current good manufacturing practices was adulterated, and although the drug worked as intended and did her no harm, she was entitled to damages under California law pursuant to breach of warranty, fraud, and unjust enrichment theories. Id. at *1. The products at issue in Myers-Armstrong were recalled at the retail level and the plaintiff did not claim any personal injury. Id. at *4. In dismissing the plaintiff's claims, the Federal District Court for the Northern District of California held that the mere fact that the product was adulterated because it was not produced in compliance with current good manufacturing practices was insufficient in the face of no actual "manifestation of a defect that results in some injury or rational fear of

injury" to state cognizable claims under California law. Id.; *see also* Mason v. Coca-Cola Co., 774 F.Supp.2d 699 (D.N.J. 2011) (dismissing claim under New Jersey Consumer Fraud Act because the plaintiff had not sufficiently alleged an ascertainable loss to support claim when the plaintiff's claim was based on violation of FDA labeling violations, reasoning "not every regulatory violation amounts to an act of consumer fraud").

Upon review of Myers-Armstrong and Mason, the Court concurs with the well reasoned decisions reached by the District Courts in California and New Jersey. Plaintiff Polk has failed to specifically allege or set forth any facts indicating the subject Medication was anything less that what it purported to be. Plaintiff points only to the Consent Decree entered into between Defendant and the FDA as the sole factual support for the claims asserted in his complaint. The Consent Decree contains no findings of fact and the Consent Decree clearly indicates that Defendant neither admits nor denies any of its claims. As stated previously, it is only evidence of a settlement negotiated between the FDA and Defendant based upon the FDA's allegations.

Plaintiff's cause of action rests entirely upon the premise that the FDA's allegations are evidence of an adulterated and defective product. Thus, Plaintiff argues the product is indisputably adulterated and defective; and worthless as a matter of law. Therefore, Plaintiff contends he has sustained an ascertainable loss under the MMPA. Plaintiff's argument is meritless. First, Plaintiff relies on allegations levied by the FDA against Defendant as conclusive evidence of "adulteration" leading to an "ascertainable loss." An allegation levied by the FDA and settled pursuant to a settlement decree devoid of any findings of fact, cannot be considered as "evidence" of any wrongdoing.

Second, Plaintiff's conclusory allegation that the Medication was adulterated and therefore worthless, without any factual support beyond a similar allegation levied by the FDA, is

insufficient to meet the ascertainable loss requirement for stating a claim under the MMPA. Plaintiff's use of the allegations levied by the FDA, and the corresponding Consent Decree entered into by the FDA and Defendant as the basis of his MMPA claim are exactly the type of "labels and conclusions" the Supreme Court cautioned against in Twombly. *See* Twombly, 550 U.S. at 555 ("[A] plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a forumlaic recitation of the elements of a cause of action will not do"). Plaintiff has failed to allege any independent facts to support his allegations that the Medication was adulterated and Plaintiff sustained an "ascertainable loss" due to the adulteration. Plaintiff cannot state a claim under the Missouri Merchandising Practices Act.

C. Breach of Implied Warranty of Merchantability

The parties disagree as to whether Missouri law or Texas law applies to the Plaintiff's breach of implied warranty of merchantability claim. Under Missouri law, in order to recover under a breach of an implied warranty of merchantability theory, "a plaintiff must prove (1) that a merchant sold goods, (2) which were not 'merchantable' at the time of the sale, (3) injury and damages to the plaintiff or his property (4) which were caused proximately or in fact by the defective nature of the goods, and (5) notice to the seller of the injury." Ragland Mills, Inc. v. General Motors, Corp., 763 S.W.2d 357, 360 (Mo. Ct. App. 1989). In order to recover for breach of the implied warranty of merchantability under Missouri law, "a plaintiff must prove that the buyer was injured by the defective nature of the goods." Renaissance Leasing, LLC v. Vermeer Mfg. Co., 322 S.W.3d 112, 130 (Mo. Ct. App. 2010).

Under Texas law, the elements of a cause of action for breach of the implied warranty of merchantability are: "1) the defendant sold or leased a product to the plaintiff; 2) the product was

unmerchantable; 3) the plaintiff notified the defendant of the breach; and 4) the plaintiff suffered an injury." Polaris Indus., Inc. v. McDonald, 119 S.W.3d 331, 336 (Tx. Ct. App. 2003). In order for a product to be unmerchantable, it must be unfit for the ordinary purposes for which it was marketed; that is to say it must have some form of a defect. Id. Once a plaintiff shows a product is unmerchantable, the plaintiff must show that the defect caused him or her to suffer injury. Id.

The parties vigorously argue over whether Missouri or Texas law applies, largely focusing on the differences between Missouri and Texas law regarding the level of notice that must be given in order to preserve a plaintiff's cause of action. Their dispute over notice is irrelevant because under both Texas and Missouri law, a plaintiff must be injured by a defect in the product he or she purchased in order to succeeds on a breach of implied warranty of merchantability claim. In the present case, Plaintiff has not alleged such a defect sufficient to maintain a claim for breach of the implied warranty of merchantability under either state's law.

Plaintiff contends that he, and others similarly situated, were prescribed and used Medication that was defective and adulterated. Plaintiff contends the Medication was unmarketable because the Medication was not manufactured and distributed in compliance with current good manufacturing practices, mirroring the allegations originally made by the FDA in its agency action. As a result, Plaintiff argues, Defendants breached the implied warranty of merchantability in that the Medication was not fit for the ordinary purposes for which such Medication is prescribed. Plaintiff, therefore, contends he and others similarly situated were injured economically and are entitled to the difference between the Medication's purchase price and its value as taken. Plaintiff does not allege that he or anyone similarly situated suffered any physical injury as a result of ingesting the Medication, or that the Medication did not adequately address the condition for which it was prescribed. Plaintiff only alleges the Medication was not

produced in compliance with current good manufacturing practices and therefore was adulterated and unfit for the ordinary purposes for which it is used. Plaintiff alleges that this "adulteration" renders the Medications's actual value to be zero dollars.

Plaintiff's breach of implied warranty of merchantability claim must fail for the same reasons that his MMPA claim fails. Plaintiff has not alleged the Medication was anything other than what it purported to be. Again, Plaintiff points only to a similar allegation by the FDA levied against KV Pharmaceutical alleging that the Medication was not manufactured in compliance with current good manufacturing practices. No conclusive findings of fact were ever made prior to a settlement being reached. The matter between the FDA and Defendants was settled via a consent decree in which Defendants did not admit to any violations whatsoever. Accordingly the FDA's allegations and the resultant Consent Decree cannot be used to bootstrap Plaintiff's claim against Defendants in the absence of any independent factual allegation by this Plaintiff that the Medication was somehow defective because it is unfit for the ordinary purposes for which it was marketed, thereby injuring the Plaintiff. Again, as with Plaintiff's MMPA claim, Plaintiff's attempts to use the allegations levied by the FDA and corresponding consent decree as the basis of his claim for breach of the implied warranty of merchantability are exactly the type of "labels and conclusions" the Supreme Court cautioned against in Twombly. *See* Twombly, 550 U.S. at 555 ("[A] plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do"). In the absence of any independent factual allegations that the Medication was anything other than Metoprolol Succinate ER, Plaintiff fails to sufficiently allege that the medication was either defective or unmerchantable as required for a sustainable breach of implied warranty of merchantability claim under either Missouri or Texas

law. Therefore, Plaintiff has not stated a breach of the implied warranty of merchantability claim upon which relief may be granted under either Texas or Missouri law.

For the above-stated reasons, the Court will grant the Defendants' motion to dismiss.

Dated this 15th day of December, 2011.

UNITED STATES DISTRICT JUDGE